



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service  
Prior Authorization Criteria

PCSK9 INHIBITORS  
PRALUENT<sup>®</sup>(alirocumab), REPATHA<sup>®</sup>(evolocumab)  
**Effective 5/24/2019**

Prior Authorization Request Form

**REPATHA** is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).
- as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

**PRALUENT** is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- as adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.

**CRITERIA FOR APPROVAL**

- 1) Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist; **AND**
- 2) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**
- 3) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL after 8-week trials each of **atorvastatin 40 - 80 mg** and **rosuvastatin 20 - 40 mg** **AND** at least one of these trials must include concurrent therapy with ezetimibe.
- 4) Should the patient be unable to tolerate 8 weeks at the recommended dosing for high-intensity statin therapy, the patient will be required to trial at least one other statin taken at the maximally tolerated dose for at least 8 weeks.

**CRITERIA FOR CONTINUATION**

Initial approval is for 90 days and documentation of efficacy must be supported by at least a 40% LDL-C reduction from pre-treatment level.



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**PCSK9 INHIBITOR MONOTHERAPY DUE TO STATIN INTOLERANCE**

WV Medicaid recognizes that there are patients with hyperlipidemia who require aggressive lipid-lowering therapy but who may not be able to safely tolerate a high-intensity statin or other lipid-lowering therapy.

Approval of any PCSK9 inhibitor requires documentation that the patient has previously failed to tolerate at least three different statins OR has experienced a potentially life-threatening adverse effect such as rhabdomyolysis while taking a statin.

**Patient statements that they have experienced muscle cramps/spasms or “myopathy” is NOT sufficient for approval as monotherapy without verifiable pharmacy claims.**

**REFERENCES**

- 1) Repatha package insert revised 2/2019
- 2) Praluent package insert revised 4/2019
- 3) Lexi-Comp Clinical Application reviewed 5/02/2019
- 4) AACE 2017 Guidelines: American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice Vol 23 (Suppl 2) April 2017.
- 5) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
- 6) Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
- 7) Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: <http://circ.ahajournals.org>.
- 8) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.
- 9) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. *Diabetes Metab Syndr Obes*. 2011; 4: 155–166.